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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/701,893      12/01/2000      Dennis Bigg      427 038      9852

20311      7590      08/08/2002

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT      PAPER NUMBER


1624

DATE MAILED: 08/08/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No. <b>09/701,893</b>	Applicant(s) <b>BIGG et al.</b>	
Examiner <b>Brenda Coleman</b>	Art Unit <b>1624</b>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 31, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3, 4, and 9-13 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 4, and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other:  |

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### **DETAILED ACTION**

Claims 3, 4 and 9-13 are pending in the application.

This action is in response to applicants' amendment dated May 31, 2002. Claim 3 and 9-11 have been amended, claim 5 has been canceled and claims 12 and 13 are newly added.

#### ***Response to Arguments***

Applicants' arguments filed May 31, 2002 have been fully considered with the following effect:

1. With regards to the 35 USC § 112, enablement rejection of claims 3, 4, 9 and 10 of the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicant's argument are that the claims "are directed to a method for blocking somatostatin receptors in warm blooded animals and to treat the diseases associated therewith as clearly set forth in the specification". A method of treating a disease which is responsive to the blocking of the somatostatin receptors, comprising the step of administering....a 7,8,9,10-tetrahydro-4H-pyrido[4',3';4,5]thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine compound as claimed in claim 10 does not provide enablement for each and every disorder claimed therein. Any evidence presented must be commensurate in scope with the claims and must clearly demonstrate the effectiveness of the claimed compounds. However, the specification provides no definitive evidence to correlate any one disorder selected from those disclosed in the specification with the instantly disclosed 7,8,9,10-tetrahydro-4H-pyrido[4',3';4,5]thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine compounds.

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No screening protocol(s) are ever described. Thus, no evidence of in vitro effectiveness is seen in the specification for one of the instantly claimed 7,8,9,10-tetrahydro-4H-pyrido[4',3';4,5]thieno[3,2-f][1,2,4]triazolo[4,3-a][1,4]diazepine compounds. In general, pharmacological activity is a very unpredictable area. In cases involving physiological activity "the scope of the enablement obviously varies inversely with the degree of unpredictability of the factors involved." *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970). Since this case involves unpredictable *in-vivo* physiological activities, the scope of the enablement given in the disclosure presented here was found to be low. There must be evidence to justify the contention that the claimed compounds can be useful in the treatment of insulin dependent diabetes, Crohn's disease, hypotension, cancers, pain, panic attack, obesity, etc..

Claims 3, 4, 9, 10, 12 and 13 are rejected under 35 USC § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. For reasons of record and stated above.

2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled b), c), d), e), f), g), h), i), j), k), l), m), n) and o) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejection labeled a) the applicant's amendments and remarks have been fully considered but they are not persuasive.

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- a) The applicants' stated that the "claim clearly calls for administering to warm-blooded animals an effective amount of the active ingredient and this is clearly a step which is well known and recognized by the Patent Office". The applicants' also stated that the applicants "have shown by the test data on page 40 that the compounds are active for the desired results". However, the claim embraces diseases and/or disorders not known to be associated with the inhibition of the somatostatin receptors. Hence the claim remains vague and indefinite in that it is not known which are the diseases capable of being mediated by blocking the activity of the somatostatin receptor(s).

Claims 3, 4, 9, 10, 12 and 13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For reasons of record and stated above.

3. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 102, anticipation rejections labeled 3, 5, 6, 7 and 8 of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 102, anticipation rejection labeled 4 of the last office action, the applicant's amendments and remarks have been fully considered but they are not persuasive.

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4. The applicants' stated that "this is excluded by the ii) disclaimer of 4-hydroxy-phenyl in the definition of R'". However the compound taught by Girault is where R<sub>1</sub> is para-chloro which is not excluded by the proviso of claim 11.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Girault et al., Chromatographia. For reasons of record and stated above.

4. With regards to the 35 USC § 103, obviousness rejection of claims 3-5 and 9-11 over Tahara et al., EP 0 638 560 of the last office action, applicant's arguments have been fully considered but are not found persuasive. The applicants' stated that the Tahara et al., reference "discloses the use of some diazepines for the treatment of osteoporosis and the measured activity is the bone resorption-inhibitory effect" and that "this in no way suggests an affinity of the said diazepines on somatostatin receptors as claimed by Applicants". While the utility of the prior art may not show the mode of action for the treatment of osteoporosis as that which is instantly urged, the discovery of an additional property does not make otherwise obvious compounds unobvious. See for example, In re Best, 195 USPQ 430; In re Dillon, 16 USPQ 2d, 1897.

Claims 3, 4 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tahara et al., EP 0 638 560. For reasons of record and stated above.

In view of the amendment dated May 31, 2002, the following new grounds of rejection apply:

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 4 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 10 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the end of claim 10 where it states that the compounds of the formula .... sufficient to "treat somatostatin receptors".
- b) Claim 11 is vague and indefinite in that it is not known what is meant by the variables  $R_{2a}$  and  $R_{2b}$  in formula II which are not defined within the claim.
- c) Claim 11 is vague and indefinite in that it is not known what is meant by the definitions of  $R'_{2a}$  and  $R'_{2b}$  in the claim since there are no variables  $R'_{2a}$  and  $R'_{2b}$  in formula II.
- d) Claim 11 is vague and indefinite in that it is not known what is meant by the proviso labeled iiiiii) where  $R'_2$  is o-chloro since there is no variable  $R'_2$  in formula II.
- e) Claim 11 is vague and indefinite in that it is not known what is meant by the proviso labeled iiiiii) where  $R'_{2b}$  is hydrogen since there is no variable  $R'_{2b}$  in formula II.

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- f) Claim 13 is vague and indefinite in that it is dependent on a canceled claim.
- g) Claim 13 is vague and indefinite in that it is not known what is meant by the list of substituents which includes seven definitions per row and the claim only references 6 substituents, i.e. R', X', R'<sub>1</sub>, R<sub>2a</sub>', R<sub>2b</sub>', and R'<sub>3</sub>.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner



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can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Brenda Coleman  
Primary Examiner AU 1624  
August 7, 2002